EXHIBIT 2

Insight Proof of Claim

B 10 (Official Form 10) (12/12)

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS

PROOF OF CLAIM

Name of Debtor:	Case Number:
NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW ENGLAND COMPOUNDING CENTER **TAX ID. NO. 04-3407495**	**12-19882-HJB**

NOTE: *Do not use this form to make a claim for an administrative expense that arises after the bankruptcy filing. You may file a request for payment of an administrative expense according to 11 U.S.C. § 503.*

Name of Creditor (the person or other entity to whom the debtor owes money or property):
Insight Health Corp.

Name and address where notices should be sent:
See attached Addendum

Telephone number: See attached Addendum
email: See attached Addendum

Name and address where payment should be sent (if different from above):
See attached Addendum

Telephone number: See attached Addendum
email: See attached Addendum

COURT USE ONLY

☐ Check this box if this claim amends a previously filed claim.

Court Claim Number: _____
(If known)

Filed on: _____

☐ Check this box if you are aware that anyone else has filed a proof of claim relating to this claim. Attach copy of statement giving particulars.

1. Amount of Claim as of Date Case Filed: $ See attached Addendum

If all or part of the claim is secured, complete item 4.

If all or part of the claim is entitled to priority, complete item 5.

☐ Check this box if the claim includes interest or other charges in addition to the principal amount of the claim. Attach a statement that itemizes interest or charges.

2. Basis for Claim: See attached Addendum
(See instruction #2)

3. Last four digits of any number by which creditor identifies debtor:	**3a. Debtor may have scheduled account as:**	**3b. Uniform Claim Identifier (optional):**
_____	_____ (See instruction #3a)	_____ (See instruction #3b)

4. Secured Claim (See instruction #4)
Check the appropriate box if the claim is secured by a lien on property or a right of setoff, attach required redacted documents, and provide the requested information.

Nature of property or right of setoff: ☐ Real Estate ☐ Motor Vehicle ☐ Other
Describe:

Value of Property: $ _____

Annual Interest Rate _____% ☐ Fixed or ☐ Variable
(when case was filed)

Amount of arrearage and other charges, as of the time case was filed, included in secured claim, if any:
$ _____

Basis for perfection: _____

Amount of Secured Claim: $ _____

Amount Unsecured: $ _____

5. Amount of Claim Entitled to Priority under 11 U.S.C. § 507 (a). If any part of the claim falls into one of the following categories, check the box specifying the priority and state the amount.

☐ Domestic support obligations under 11 U.S.C. § 507 (a)(1)(A) or (a)(1)(B).

☐ Wages, salaries, or commissions (up to $11,725*) earned within 180 days before the case was filed or the debtor's business ceased, whichever is earlier – 11 U.S.C. § 507 (a)(4).

☐ Contributions to an employee benefit plan – 11 U.S.C. § 507 (a)(5).

Amount entitled to priority:

☐ Up to $2,600* of deposits toward purchase, lease, or rental of property or services for personal, family, or household use – 11 U.S.C. § 507 (a)(7).

☐ Taxes or penalties owed to governmental units – 11 U.S.C. § 507 (a)(8).

☐ Other – Specify applicable paragraph of 11 U.S.C. § 507 (a)(_____).

$ _____

******Amounts are subject to adjustment on 4/1/13 and every 3 years thereafter with respect to cases commenced on or after the date of adjustment.*

6. Credits. The amount of all payments on this claim has been credited for the purpose of making this proof of claim. (See instruction #6)

7. Documents: Attached are **redacted** copies of any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, security agreements, or, in the case of a claim based on an open-end or revolving consumer credit agreement, a statement providing the information required by FRBP 3001(c)(3)(A). If the claim is secured, box 4 has been completed, and **redacted** copies of documents providing evidence of perfection of a security interest are attached. If the claim is secured by the debtor's principal residence, the Mortgage Proof of Claim Attachment is being filed with this claim. *(See instruction #7, and the definition of "**redacted**".)*

DO NOT SEND ORIGINAL DOCUMENTS. ATTACHED DOCUMENTS MAY BE DESTROYED AFTER SCANNING.

If the documents are not available, please explain:

8. Signature: (See instruction #8)

Check the appropriate box.

☐ I am the creditor. ☒ I am the creditor's authorized agent. ☐ I am the trustee, or the debtor, or their authorized agent. (See Bankruptcy Rule 3004.) ☐ I am a guarantor, surety, indorser, or other codebtor. (See Bankruptcy Rule 3005.)

I declare under penalty of perjury that the information provided in this claim and in the attached "PITWD Addendum" (if required and submitted) is true and correct to the best of my knowledge, information, and reasonable belief.

Print Name: James F. Stanley
Title: Chief Financial Officer
Company: Insight Health Corp.
Address and telephone number (if different from notice address above):
5775 Wayzata Boulevard, Suite 400
Minneapolis, MN 55416

Telephone number: 952-543-6500 email:

James F. Stanley 12/20/2013
(Signature) (Date)

Penalty for presenting fraudulent claim: Fine of up to $500,000 or imprisonment for up to 5 years, or both. 18 U.S.C. §§ 152 and 3571.

INSTRUCTIONS FOR PROOF OF CLAIM FORM

The instructions and definitions below are general explanations of the law. In certain circumstances, such as bankruptcy cases not filed voluntarily by the debtor, exceptions to these general rules may apply.

Items to be completed in Proof of Claim form

IF YOU ARE ASSERTING A CLAIM FOR PERSONAL INJURY, PLEASE COMPLETE, SIGN AND RETURN THE ENCLOSED CONFIDENTIAL PERSONAL INJURY OR WRONGFUL DEATH CLAIM INFORMATION FORM (THE "PITWD ADDENDUM"). DO NOT INCLUDE ANY MEDICAL INFORMATION IN YOUR ANSWERS TO THE QUESTIONS ON THIS FORM. INSTEAD INCLUDE PRIVATE MEDICAL INFORMATION ONLY IN YOUR ANSWERS TO THE QUESTIONS IN THE PITWD ADDENDUM

Court, Name of Debtor, and Case Number:
Fill in the federal judicial district in which the bankruptcy case was filed (for example, Central District of California), the debtor's full name, and the case number. If the creditor received a notice of the case from the bankruptcy court, all of this information is at the top of the notice.

Creditor's Name and Address:
Fill in the name of the person or entity asserting a claim and the name and address of the person who should receive notices issued during the bankruptcy case. A separate space is provided for the payment address if it differs from the notice address. The creditor has a continuing obligation to keep the court informed of its current address. See Federal Rule of Bankruptcy Procedure (FRBP) 2002(g).

1. Amount of Claim as of Date Case Filed:
State the total amount owed to the creditor on the date of the bankruptcy filing. Follow the instructions concerning whether to complete items 4 and 5. Check the box if interest or other charges are included in the claim.

2. Basis for Claim:
State the type of debt or how it was incurred. Examples include goods sold, money loaned, services performed, personal injury/wrongful death, car loan, mortgage note, and credit card. If the claim is based on delivering health care goods or services, limit the disclosure of the goods or services so as to avoid embarrassment or the disclosure of confidential health care information. You may be required to provide additional disclosure if an interested party objects to the claim.

3. Last Four Digits of Any Number by Which Creditor Identifies Debtor:
State only the last four digits of the debtor's account or other number used by the creditor to identify the debtor.

3a. Debtor May Have Scheduled Account As:
Report a change in the creditor's name, a transferred claim, or any other information that clarifies a difference between this proof of claim and the claim as scheduled by the debtor.

3b. Uniform Claim Identifier:
If you use a uniform claim identifier, you may report it here. A uniform claim identifier is an optional 24-character identifier that certain large creditors use to facilitate electronic payment in chapter 13 cases.

4. Secured Claim:
Check whether the claim is fully or partially secured. Skip this section if the claim is entirely unsecured. (See Definitions.) If the claim is secured, check the box for the nature and value of property that secures the claim, attach copies of lien documentation, and state, as of the date of the bankruptcy filing, the annual interest rate (and whether it is fixed or variable), and the amount past due on the claim.

5. Amount of Claim Entitled to Priority Under 11 U.S.C. § 507 (a).
If any portion of the claim falls into any category shown, check the appropriate box(es) and state the amount entitled to priority. (See Definitions.) A claim may be partly priority and partly non-priority. For example, in some of the categories, the law limits the amount entitled to priority.

6. Credits:
An authorized signature on this proof of claim serves as an acknowledgment that when calculating the amount of the claim, the creditor gave the debtor credit for any payments received toward the debt.

7. Documents:
Attach redacted copies of any documents that show the debt exists and a lien secures the debt. You must also attach copies of documents that evidence perfection of any security interest and documents required by FRBP 3001(c) for claims based on an open-end or revolving consumer credit agreement or secured by a security interest in the debtor's principal residence. You may also attach a summary in addition to the documents themselves. FRBP 3001(c) and (d). If the claim is based on delivering health care goods or services, limit disclosing confidential health care information. Do not send original documents, as attachments may be destroyed after scanning.

8. Date and Signature:
The individual completing this proof of claim must sign and date it. FRBP 9011. If the claim is filed electronically, FRBP 5005(a)(2) authorizes courts to establish local rules specifying what constitutes a signature. If you sign this form, you declare under penalty of perjury that the information provided is true and correct to the best of your knowledge, information, and reasonable belief. Your signature is also a certification that the claim meets the requirements of FRBP 9011(b). Whether the claim is filed electronically or in person, if your name is on the signature line, you are responsible for the declaration. Print the name and title, if any, of the creditor or other person authorized to file this claim. State the filer's address and telephone number if it differs from the address given on the top of the form for purposes of receiving notices. If the claim is filed by an authorized agent, provide both the name of the individual filing the claim and the name of the agent. If the authorized agent is a servicer, identify the corporate servicer as the company. Criminal penalties apply for making a false statement on a proof of claim.

SUBMIT CLAIM TO DONLIN, RECANO & CO. IN ACCORDANCE WITH ENCLOSED INSTRUCTIONS

DEFINITIONS

Debtor
A debtor is the person, corporation, or other entity that has filed a bankruptcy case.

Creditor
A creditor is a person, corporation, or other entity to whom debtor owes a debt that was incurred before the date of the bankruptcy filing. See 11 U.S.C. §101 (10).

Claim
A claim is the creditor's right to receive payment for a debt owed by the debtor on the date of the bankruptcy filing. See 11 U.S.C. §101 (5). A claim may be secured or unsecured.

Proof of Claim
A proof of claim is a form used by the creditor to indicate the amount of the debt owed by the debtor on the date of the bankruptcy filing.

Secured Claim Under 11 U.S.C. § 506 (a)
A secured claim is one backed by a lien on property of the debtor. The claim is secured so long as the creditor has the right to be paid from the property prior to other creditors. The amount of the secured claim cannot exceed the value of the property. Any amount owed to the creditor in excess of the value of the property is an unsecured claim. Examples of liens on property include a mortgage on real estate or a security interest in a car. A lien may be voluntarily granted by a debtor or may be obtained through a court proceeding. In some states, a court judgment is a lien.

A claim also may be secured if the creditor owes the debtor money (has a right to setoff).

Unsecured Claim
An unsecured claim is one that does not meet the requirements of a secured claim. A claim may be partly unsecured if the amount of the claim exceeds the value of the property on which the creditor has a lien.

Claim Entitled to Priority Under 11 U.S.C. § 507 (a)
Priority claims are certain categories of unsecured claims that are paid from the available money or property in a bankruptcy case before other unsecured claims.

Redacted
A document has been redacted when the person filing it has masked, edited out, or otherwise deleted, certain information. A creditor must show only the last four digits of any social-security, individual's tax-identification, or financial-account number, only the initials of a minor's name, and only the year of any person's date of birth. If the claim is based on the delivery of health care goods or services, limit the disclosure of the goods or services so as to avoid embarrassment or the disclosure of confidential health care information.

Evidence of Perfection
Evidence of perfection may include a mortgage, lien, certificate of title, financing statement, or other document showing that the lien has been filed or recorded.

INFORMATION

Acknowledgment of Filing of Claim
To receive acknowledgment of your filing, you may either enclose a stamped self-addressed envelope and a copy of this proof of claim or you may access the claims agent's website (www.donlinrecano.com/necp) to view your filed proof of claim.

Offers to Purchase a Claim
Certain entities are in the business of purchasing claims for an amount less than the face value of the claims. One or more of these entities may contact the creditor and offer to purchase the claim. Some of the written communications from these entities may easily be confused with official court documentation or communications from the debtor. These entities do not represent the bankruptcy court or the debtor. The creditor has no obligation to sell its claim. However, if the creditor decides to sell its claim, any transfer of such claim is subject to FRBP 3001(e), any applicable provisions of the Bankruptcy Code (11 U.S.C. § 101 *et seq.*), and any applicable orders of the bankruptcy court.

UNITED STATES BANKRUPTCY COURT
DISTRICT OF MASSACHUSETTS

In re:	:	
	:	Chapter 11
NEW ENGLAND COMPOUNDING PHARMACY, INC.,	:	Case No. 12-19882 (HJB)
Debtor.	:	

ADDENDUM TO PROOF OF CLAIM OF INSIGHT HEALTH CORP.

Insight Health Corp. ("Insight" or "Claimant") hereby submits this Proof of Claim against New England Compounding Pharmacy, Inc. ("NECC" or the "Debtor"), a debtor in the above-captioned chapter 11 case, in accordance with the Order (a) Establishing Deadline For Submitting Proofs Of Claim, (b) Approving Certain Additional Requirements And Procedures For Personal Injury Tort and Wrongful Death Claims and (c) Approving Form And Manner Of Notice Thereof (Docket No. 582), dated September 27, 2013 (the "Bar Date Order").

EXECUTIVE SUMMARY

1. As described in greater detail below, this Proof of Claim (as defined below) asserts claims (the "Claims") that Insight has, or may have, against NECC on account of, or related to, products, including, but not limited to, the Recalled Lots (as defined below), from NECC. The Claims include, but are not limited to, contribution, indemnification, actual fraud, constructive fraud, negligence, gross negligence, breach of express warranty, and breach of implied warranty.

INTRODUCTION

2. Debtor was a supplier/producer/manufacturer of compounded methylprednisolone acetate ("MPA"), which was provided to Insight, among many others, for use in epidural steroid injections of individuals experiencing chronic pain. The MPA was typically injected into the spinal column of the individual to reduce inflammation and eliminate pain.

3. Insight is a company that operates imaging centers nationwide, including a facility located in Roanoke, Virginia. Patients at Insight's Roanoke clinic receive, among other services, image-guided pain therapy. Insight performs the clinic administration and operational support functions at the Roanoke facility. Insight's Roanoke clinic received preservative-free MPA from NECC over a 5-year period.

4. NECC represented to Insight that it produced quality drugs and that NECC was a safe and reliable source for compounded medication. NECC also represented to Insight that it was properly licensed in all 50 states, including Massachusetts and Virginia and in compliance with all relevant regulations, statutes, standards, and guidelines, including those set forth in the United States Pharmacopeia and the National Formulary ("USP-NF") and the Virginia Drug Control Act, Va. Code § 54.1-3400, *et seq*.

5. Insight relied upon these representations, licensures, and certifications, and based on those representations, licensures, and certifications, Insight believed that NECC was a safe, reputable, and reliable source of preservative-free MPA and, therefore, the preservative-free MPA was purchased from NECC for Insight's patients who needed epidural steroid injections.

A. NECC-Related Outbreak

6. On or about September 18, 2012, the Centers for Disease Control ("CDC") traced the first case of fungal meningitis to an epidural steroid injection of preservative-free MPA

produced by NECC and administered to a patient in Tennessee. By late September 2012, NECC informed the Food and Drug Administration ("FDA") that 17,500 vials of MPA had been sent to 75 facilities in 23 states.

7. The FDA and CDC investigated the outbreak and identified fungus and/or other impurities in samples taken from multiple lots of MPA. The FDA and CDC identified NECC as the source of the contaminated MPA and instituted a recall of certain identified lots of MPA that had been prepared and sold by NECC.

8. On September 26, 2012, NECC recalled three MPA lots, numbered 05212012@68, 06292012@26, and 08102012@51 (the "Recalled Lots"). This recall was the first public notice of any problems with these lots.

9. On or about October 3, 2012, the Massachusetts Board of Registration in Pharmacy secured the surrender of NECC's license to operate as a compounding pharmacy.

10. On October 6, 2012, the FDA and CDC instituted a recall of all NECC products. Healthcare professionals and clinics around the country, including Insight, were told to stop using all NECC products immediately and until further notice from the FDA.

B. NECC's Representations About Quality And Sterility

11. Among the many representations made by NECC, Insight was told that the Recalled Lots had been examined, tested, and analyzed by ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") prior to the outbreak. In addition, NECC regularly provided certificates of ARL's analyses along with each shipment of MPA. *See* ARL Certificates of Analysis and Microbiology Reports, attached hereto as Exhibit A.

12. NECC represented that it complied with United States Pharmacopeia ("USP") 797, which requires end-product testing, by submitting its product to ARL for independent third-

party testing. ARL certified that its testing of NECC products, including those tests done on the contaminated lots, complied with USP 71 requirements, meaning that an appropriately-sized sample of each batch was supposed to have been cultured and tested to show that the end products were sterile. This representation, upon which Insight relied, was false, and NECC knew that the samples it submitted to ARL for testing were not of a sufficient size to satisfy the requirements of USP 71.

13. Insight believes that ARL and NECC collaborated and ARL therefore falsely and fraudulently represented on its laboratory reports and related documents that its testing of NECC's products complied with USP 71. NECC caused this to happen with full knowledge and intention that these documents would be reviewed by and relied on by its customers, including Insight.

14. All of the Recalled Lots tested by ARL were represented to be "sterile," and reports certifying the sterility of these lots were shipped to NECC's customers, including Insight. These false reports accompanied the contaminated product. (*See* Exhibit A.)

15. NECC's customers, including Insight, relied on these reports as further proof of NECC's safety and quality control measures and compliance with all applicable guidelines. NECC led Insight to believe that these reports accurately reflected the condition of the product they received from NECC and certified that the product was sterile and safe for use as intended. Based on these reports, as well as other information and materials received from NECC, physicians at Insight's clinic unknowingly injected their patients with contaminated preservative-free MPA.

16. Moreover, Linda Pino, Mark Zachem, Michael Thurston, Andrew Howden, and Chad Trudeau, each a sales representative on behalf of NECC, distributed NECC policies,

brochures, and other marketing materials to its customers and potential customers, highlighting NECC's safety and sterility practices and the high quality of NECC's products, including preservative-free MPA.

17. Between January 2012 and August 2012, NECC's environmental monitoring program found bacteria and mold in the "clean room" that was used for the production of preservative-free MPA. NECC did not disclose this fact to Insight or any other customer of NECC. Moreover, NECC failed to investigate the reported presence of bacteria and mold in the "clean room," even though NECC knew or should have known that the presence of bacteria and mold in an environment where sterile products are produced presented a grave risk to NECC's customers and to the patients who were to receive the preservative-free MPA produced at the NECC facility.

18. Since at least 2011, NECC provided "Quality Assurance Report Cards" to its customers to highlight the safety and sterility of its facility and its products. For instance, the Quality Assurance Report Card for the second quarter of 2012 (the "Report Card"), stated that the purpose of the Report Card was to provide the "most recent review of NECC's product, personnel, facilities and quality systems. This Report Card may be kept on file and referred to during various hospital inspections by the Joint Commission and your local, state, and federal regulatory agencies as third party service provider substantiation." *See* Quality Assurance Report Card, Quarter 2, 2012, attached as Exhibit B.

19. According to NECC, the Report Card "is in place to evaluate our internal quality systems each quarter to ensure that we are meeting the associated requirements outlined in USP 797 'Pharmaceutical Compounding – Sterile Preparations.'" (*Id.*)

20. The Report Card further assured its customers that the Report Card assists all of our customers in complying with USP 797." (*Id.*)

21. NECC further pledged in its Report Card, under the title "Our Commitment" that "NECC . . . is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers." (*Id.*)

22. Specifically, for the second quarter of 2012, which is the last quarter before the fungal meningitis outbreak from its products, NECC represented that the "results of our internal review for the 2nd Quarter 2012, ending June 30th, demonstrate that NECC meets and is in continued compliance with all applicable requirements and standards. This review exhibits that our existing quality systems and facilities are in a state of control." (*Id.*)

23. The Report Card was endorsed by Barry Cadden, Pharmacy Director for NECC and one of NECC's principals. (*Id.*)

24. NECC further provided to NECC customers various marketing materials touting NECC's quality standards, quality control measures, and overall compliance with regulations, guidelines, and statutes. For example, a "General Overview of Policies and Procedures for Compounding Sterile Products" purportedly outlined the safety measures and regulations with which NECC had complied with regard to its pharmaceutical products, including MPA. *See* NECC Brochure, attached as Exhibit C. The representations made by NECC in its marketing material were relied upon in connection with Insight's purchase of products from NECC. These marketing materials, distributed by NECC to its customers, including Insight, represented and warranted that NECC:

a. was compliant with "Class 10 microenvironment (barrier isolator)";

b. was certified by the Massachusetts Board of Pharmacy;

c. had its microenvironments validated every six months by an independent vendor;

d. hired only trained and validly registered pharmacists;

e. trained and validated its pharmacy personnel through Professional Compounding Centers of America, an independent certifying agency;

f. re-validated all personnel on a quarterly basis;

g. used only USP chemicals obtained from FDA registered facilities;

h. sterilized all formulas through either filtration or autoclaving;

i. had all batches tested and certified for sterility by ARL, an independent laboratory;

j. allowed no medication to leave the NECC facility without first being tested and certified by ARL to ensure sterility and potency;

k. allowed no medication to leave the NECC facility unless and until ARL made a definitive determination that the medication was sterile and free of contamination;

l. abided by standard operating procedures that were "mapped against" USP 797 and complied with USP 797; and

m. was compliant with all licensing requirements in all 50 states.

25. Following the outbreak, the Massachusetts Board of Registration in Pharmacy and the FDA investigated and identified serious deficiencies and violations at NECC's facility that placed the public's health and safety at risk. Each agency released a report outlining NECC's prior history of various safety violations, including other instances of contaminated products in 2002 and 2006. Notably, this information had not been released to the public or otherwise made publically available prior to October 2012.

26. On October 11, 2012, the FDA announced that it had found fungal contaminants in multiple sealed vials of MPA produced by NECC.

27. On October 23, 2012, the Massachusetts Board of Registration in Pharmacy released the findings from its investigation. These findings were similar to those of the FDA, issued on October 26, 2012. These reports identified, among others, the following violations of pharmacy law and regulations that placed the public's safety at risk:

- Visible black particulate matter was seen in several recalled sealed vials of MPA from Lot#08102012@51;
- Powder hoods, intended to protect pharmacists from inhaling substances during the compounding process, were not thoroughly cleaned in violation of USP 797. Residual powder was observed with in the hood unit, which could lead to subsequent contamination of compounded medications;
- "Tacky" mats located near the "clean room," used to trap dust, dirt, and other impurities from shoes were visibly soiled with assorted debris;
- A leaking boiler adjacent to the "clean room" created an environment susceptible to contaminant growth due to pooling water;
- Surface samples from the "clean room" showing bacteria and mold growth;
- Samples taken from equipment in and around the "clean room" revealed the presence of bacteria and mold;
- Other unsterile conditions, such as discoloration lining the interior surfaces of the autoclave instrument used to sterilize compounding components;
- The air ducts and air filtering system for the facility contained evidence of airborne contamination;

- External HVAC equipment was located within feet of a garbage and/or waste recycling facility that operated adjacent to NECC;
- A white powder substance was found around the HVAC return grate located behind the autoclave instrument used for sterilization; and
- Failures on the part of NECC's own environmental monitoring program that identified bacteria and mold yet failed to take any action to correct these conditions.

28. In 2011 the Massachusetts Board of Registration in Pharmacy inspected and reviewed NECC's operations after it moved its facility to the Waverly Street location. Despite the numerous problems identified by the FDA and other organizations, the Massachusetts Board of Registration in Pharmacy found the facility and its practices to be "satisfactory." As a result, NECC maintained its license to practice pharmacy.

29. Insight reasonably relied on the investigation and regulation of NECC by the Massachusetts Board of Registration in Pharmacy and specifically relied on the standards and quality control regulations purportedly imposed by the Massachusetts Board of Registration on its licensees.

LAWSUITS AND POTENTIAL CLAIMS AGAINST INSIGHT RELATING TO NECC'S MPA

30. Insight is currently a named defendant in 22 lawsuits filed in the Circuit Court for the City of Roanoke, Virginia, alleging injuries and, in some cases, death, resulting from the administration of injections containing contaminated MPA that was marketed, manufactured,

produced, and shipped by NECC (hereinafter the "Roanoke Suits"). A listing of each of the 22 lawsuits is attached hereto as Exhibit D.[1]

31. The extent of injury suffered by each plaintiff in the Roanoke Suits is the subject of ongoing, and as yet incomplete, discovery. Insight's information about the extent of injuries in some cases is limited to the allegations in the respective complaints. Nevertheless, each of the 22 complaints alleges that the plaintiff contracted fungal meningitis and had to undergo, in some cases, hospitalization and other extensive treatment for the infection. Three of the Roanoke Suits include wrongful death claims. Each of the *ad damnum* clauses in 20 of the 22 complaints in the Roanoke Suits seek compensatory damages of $5 million, and one such complaint seeks compensatory damages of over $25 million (the remaining two seek $2 million and $500,000, respectively). All but one of the 22 Roanoke Suits also seeks punitive damages of $350,000. Combined, the Roanoke Suits seek well over $100 million in damages. This Proof of Claim hereby asserts claims for each of the grounds set forth below on account of each of the Roanoke Suits.

32. In addition to the Roanoke Suits, upon information and belief, and subject to further inquiry, there may be additional potential claimants who may have received injections of MPA from NECC at Insight's facility in Roanoke who may allege damages, injuries, and/or death resulting from such injections (the "Potential Roanoke Claims"). Insight reserves the right to supplement its Proof of Claim with additional information about specific Potential Roanoke Claims in the event that those potential claims mature into demands for payment and/or lawsuits. Nevertheless, this Proof of Claim hereby asserts claims against NECC for each of the grounds set

[1] The complaints in each of the 22 lawsuits are voluminous and, for this reason, Insight has not attached them to its Proof of Claim. In the event that the Trustee wishes to receive copies of each complaint, Insight will provide them to the Trustee.

forth below on account of each Potential Roanoke Claim that becomes an actual claim against Insight.

INSIGHT'S CLAIMS AGAINST NECC

33. Insight did not alter the MPA received from NECC. NECC represented to Insight that the MPA was a sterile, preservative-free preparation of MPA for use in intrathecal and other injections. The vials of MPA were kept unopened, in the original sealed vials as received from NECC, until immediately prior to being used by the physicians in a procedure. Even at the point when the seals on the vials were removed, the vials remained sealed with a rubber membrane so no contaminants could enter the vial. The MPA was agitated, then drawn into a sterile syringe, using sterile technique, and then injected unaltered into patients. To the extent that any patient in Insight's Roanoke facility received contaminated MPA, such contaminated MPA came from NECC and was purchased by Insight and used by the physicians at the Insight facility, without any knowledge of any potential contamination.

34. Insight denies any and all liability for any injuries, damages and death claimed with respect to the Roanoke Suits and the Potential Roanoke Claims. If any of the plaintiffs in any of Roanoke Suits obtains a judgment against Insight, all damages allegedly sustained by the plaintiff were solely the result of the acts, omissions, breaches, negligence, fraud and/or other violations of law by NECC. Similarly, if any of the potential plaintiffs with respect to the Potential Roanoke Claims obtains a judgment against Insight, all damages allegedly sustained by such potential plaintiff were solely the result of the acts, omissions, breaches, negligence, fraud and/or other violations of law by NECC.

35. Contribution. In the event that Insight incurs an adverse judgment with respect to the Roanoke Suits and the Potential Roanoke Claims, Insight is entitled to contribution from

NECC for each and every such judgment. *See* Va. Code 8.01-34; *Hudgins v. Jones*, 205 Va. 495, 138 S.E.2d 16 (1964).

36. Indemnification. In the alternative, in the event that Insight incurs an adverse judgment with respect to any of the Roanoke Suits or the Potential Roanoke Claims, Insight is entitled to common law equitable indemnification from NECC for each and every such judgment because NECC was the negligent party whose conduct proximately caused the injury of the plaintiffs or potential plaintiffs with respect to the Roanoke Suits or the Potential Roanoke Claims, without any intervention or other action by Insight. *See e.g., Carr v. The Home Ins. Co.*, 250 Va. 427, 429, 463 S.E.2d 457 (1995).

37. In addition, with respect to the Roanoke Suits or the Potential Roanoke Claims, Insight is entitled to implied indemnity—sometimes referred to as an implied contract for indemnity or implied-in-fact indemnity—because, as described below, NECC breached its implied warranty of merchantability to Insight. *See Whittle v. Timesavers, Inc.*, 614 F. Supp. 115, 119 (W.D. Va. 1985) ("[W]here there has been a breach of an implied warranty of merchantability . . . an implied contract for indemnity will lie."); *see also Wingo v. Celotex Corp.*, 834 F.2d 375, 377 (4th Cir. 1987) ("The general law is that where a supplier of chattels supplies a dangerously defective chattel to a buyer for the use of another and both have become liable to the user on account of the use of the product, an implied right of indemnity in favor of the buyer against the supplier is usually implied.").

38. Moreover, if Insight is found to be at fault in some regard with respect to the Roanoke Suits or the Potential Roanoke Claims, NECC's negligence was greater in quality and degree and, therefore, Insight is entitled to implied-in-law indemnity. *See, e.g., International Surplus Lines Ins. Co. v. Marsh & McLennan, Inc.*, 838 F. 2d 124, 126-127 (4th Cir. 1987).

39. Accordingly, Insight is entitled to recover from NECC 100% of each and every adverse judgment or settlement relating to the Roanoke Suits and the Potential Roanoke Claims, including all attorneys' fees and other costs of defense.

40. Actual and/or Constructive Fraud. NECC fraudulently represented to its customers, including Insight, that it was a high-quality pharmacy that was properly licensed to sell its compounded pharmaceuticals in all 50 states including the Commonwealth of Virginia; and that its preservative-free MPA was a high-quality, sterile formulation acceptable for intrathecal administration and prepared in accordance with USP 797 standards. NECC fraudulently concealed its lack of compliance with controlling regulations and standards, including USP 797, from Insight and its other customers. NECC also fraudulently concealed its prior investigations and citations by the Massachusetts Board of Registration in Pharmacy and the FDA.

41. Insight relied to its detriment on the numerous false representations by NECC, including the laboratory reports indicating sterility, and experienced actual injury as a result of NECC's fraudulent and false statements.

42. Insight has been injured in that its reputation has been damaged in the Roanoke community, it has lost goodwill, and it has been sued in 22 separate lawsuits by individuals claiming that they were harmed by NECC's MPA, leading to liability exposure, attorney's fees and costs. Insight seeks compensatory and exemplary damages for fraud from NECC, as well as its attorneys' fees, costs of suit, interest and such other relief as is proper.

43. Negligence. NECC had a duty to its customers, including Insight, to ensure that the product developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce: (a) complied with all

applicable statutes, regulations, guidelines, and/or industry standards; (b) was safe for use as intended; (c) was sterile; and (d) was free of contamination.

44. NECC breached this duty by developing, designing, testing, manufacturing, inspecting, labeling, distributing, marketing, promoting, selling, and otherwise releasing into commerce a product that did not comply with applicable statutes, regulations, guidelines, and/or industry standards; was not safe for its intended use; was not sterile; and/or was not free of contamination.

45. NECC's breach of duties directly and proximately caused further injury to Insight, including, but not limited to, loss of reputation, lost income, liability exposure, and attorneys' fees and related litigation costs.

46. Gross Negligence. The acts and omissions of NECC did not meet the most minimal diligence to ensure that it was not selling, testing, distributing, certifying, promoting, marketing, and/or otherwise providing contaminated MPA to its customers, including Insight. In fact, NECC purposely failed to disclose to any of its customers, including Insight, that NECC had been cited, reprimanded, penalized and/or faced probationary measures at various times in the past for violating sterility and other standards pertaining to compounding drugs by the FDA and/or the Massachusetts Board of Registration in Pharmacy, despite knowing or having constructive knowledge of all such facts.

47. Rather, NECC promoted itself as compliant with all relevant regulations and standards, compliant with safety and quality control measures, reliable due to the use of independent, certified laboratory testing and a competent producer of safe, sterile, pharmaceutical products.

48. The acts and omissions of the Debtor constituted such utter disregard for the rights of others and for safety as to be intentional and/or so unreasonable as to constitute gross negligence. The acts and omissions of NECC were a heedless and palpable violation of its legal duties respecting life, rights and safety of the consumers of its products. *See Frazier v. City of Norfolk*, 234 Va. 388, 393 (1987).

49. Insight has been damaged and injured as a result of NECC's gross negligence and recklessness including injury to its business reputation and goodwill, potential liability exposure, attorneys' fees, and costs.

50. Breach of Express Warranty. NECC advertised, labeled, marketed, tested, certified, and/or promoted its MPA, representing the quality and safety of the product to health care providers and consumers, including Insight, in such a way as to induce its purchase or use, thereby making an express warranty that the MPA conformed to the representations. Such representations included that the MPA was preservative free and sterile and that it was safe for intrathecal injection into human beings. More specifically, NECC sent promotional materials to one of the physicians practicing at Insight's Roanoke clinic specifically warranting that (see Exhibit C):

- NECC "complies with USP Chapter 797 Guidelines for Aseptic Compounding";
- NECC's "facility was designed and built as a compounding-only pharmacy with a strong focus on sterile products";
- "Sterile fluids and injectables are prepared in a Class 10 Microenvironment (barrier isolator)";
- NECC's "clinically trained pharmacists" were "licensed and registered with the Massachusetts Board of Registration in Pharmacy," have "completed American

Council on Pharmaceutical Education accredited aseptic training courses," and follow "national standards of practice for sterile product preparation as set forth by . . . the American Society of Health-System Pharmacists . . . and the United States Pharmacopeia . . . .";

- NECC maintains "extensive Environmental Testing and Quality Assurance Programs"; and
- NECC "uses an independent lab to test applicable medications for sterility, potency and pyrogenicity".

51. NECC also included a "General Overview of Policies & Procedures for Compounding Sterile Products," listing in outline form each of the safety and quality measures employed by NECC to ensure that its products were sterile, safe for injection, and otherwise of high quality. (Exhibit C.)

52. These representations individually and collectively were specific warranties intended by NECC to accompany its products and to assure its customers, including Insight, that NECC's sterile compounded pharmaceuticals were as safe for use as any comparable product produced by a pharmaceutical manufacturer.

53. NECC breached these warranties by failing to maintain the environmental and other safety controls in place as warranted in its targeted promotional documents sent to Insight. More specifically, NECC's practices failed to comply with USP 797, USP 71, failed to maintain the integrity of its Class 10 Microenvironment, failed to provide trustworthy and reliable independent lab testing reports concerning the sterility of NECC's product, and generally failed to provide a safe, reliable and effective product for use by Insight and the physicians practicing at Insight's Roanoke Clinic.

54. As a direct and proximate result of NECC's breach of warranty, patients were purportedly injected with contaminated MPA, and Insight has been damaged by the loss of its reputation, goodwill, potential exposure to liability, attorneys' fees and other costs of defense.

55. Breach of Implied Warranty of Fitness for Particular Purpose. NECC advertised, labeled, marketed, tested, certified, and/or promoted its MPA, representing the quality and safety of the product to health care providers and consumers, including Insight, in such a way as to induce its purchase or use, thereby making an express warranty that the MPA conformed to the representations. Such representations included that the MPA was preservative free and sterile and that it was safe for intrathecal injection into human beings.

56. The MPA advertised, labeled, marketed, tested, certified, and/or promoted by NECC did not conform to the representations made, in that the MPA was not safe and effective for its intended use. Insight, through the use of reasonable care, could not have discovered NECC's breach of warranty or learned that the MPA was not sterile.

57. The breach of warranty was a material factor in causing injury to the plaintiffs in the Roanoke Suits listed in Exhibit A, any potential plaintiffs with respect to the Potential Roanoke Claims and to NECC's customers, including Insight.

58. As a direct and proximate result of NECC's breach of warranty, patients were purportedly injected with contaminated MPA, and Insight has been damaged by the loss of its reputation, goodwill, potential exposure to liability, attorneys' fees and other costs of defense.

59. Breach of Implied Warranty of Merchantability. The MPA advertised, labeled, marketed, tested, certified, and promoted by NECC was not of merchantable quality nor was it fit for the ordinary purposes for which such medicines are intended to be used, and did not meet the expectations for the performance of the product when used in the customary, usual, and

reasonably foreseeable manner, nor was it minimally safe for the expected or intended purpose to which the MPA would be put.

60. Insight could not have, through reasonable care, discovered the breached warranty and realized the danger that breach posed. NECC knew or should have known that Insight was within the class of entities which would have reasonably been expected to use the MPA, and/or provide the MPA to physicians for use with patients.

61. Insight has sustained damages as a direct and proximate result of the breach of the implied warranty of merchantability, and as a direct and proximate result of NECC's breach of the implied warranty of merchantability, patients were purportedly injected with contaminated MPA and Insight has been damaged by the loss of its reputation, goodwill, potential exposure to liability, attorneys' fees and other costs of defense.

62. Miscellaneous. The assertion of the above claims by Insight against NECC is in addition to any other claims, of any kind or nature whatsoever, in law or in equity, that Insight might have, on account of, or related to, any products, including, but not limited to, the Recalled Lots, from NECC.

Damages Owed by NECC to Insight

63. As a result of the actions, omissions, breaches, negligence, fraud, and violations of controlling standards and laws set forth above, NECC is indebted to Insight for the following unliquidated amounts, among others:

- Any and all amounts paid to satisfy any adverse judgment against Insight in any of the Roanoke Suits and the Potential Roanoke Claims;
- Any and all amounts paid to settle any of the Roanoke Suits and the Potential Roanoke Claims;

- Damages for Insight's loss of business, loss of goodwill, injury to reputation, and business disruption caused by NECC providing contaminated MPA to Insight;
- Insight's costs of defending itself against the Roanoke Suits and the Potential Roanoke Claims, including its attorneys' fees, litigation costs, expert witness fees, and other expenses;
- Any and all other amounts incurred by Insight as a result of NECC's conduct described herein.

64. The Debtor may be further indebted or liable to the Claimant in additional unliquidated amounts.

* * *

65. The attached proof of claim form, together with this Addendum (the "Proof of Claim"), asserts a claim against the Debtor. This Proof of Claim is filed to protect and preserve the rights and remedies of the Claimant as they relate to the Roanoke Suits and the Potential Roanoke Claims. Nothing herein shall be deemed to be a waiver of any rights that the Claimant may have under or with respect to any of the foregoing. The Claimant reserves all of its rights and claims that it may have against the Debtor.

66. The Claimant expressly reserves the right to file additional claims against the Debtor, whether or not related to this Proof of Claim. The Claimant further expressly reserves the right to amend, modify or supplement this Proof of Claim in any manner and for any purpose, including, without limitation (a) amending, updating, or supplementing this Proof of Claim (including, without limitation, to add additional amounts due and owing) at any time and in any respect, (b) amending this Proof of Claim to assert any rights that the Claimant may have to setoff, offset, or recoup amounts under 11 U.S.C. § 553 or otherwise against any claims,

defenses, or offsets the Debtor may assert against the Claimant, and (c) filing a request for payment of administrative or priority expenses in accordance with 11 U.S.C. § 503 and 11 U.S.C. § 507. Further, the Claimant reserves the right to file one or more motions or other appropriate pleadings requesting the allowance and payment of any claims which arise postpetition and which constitute administrative expense claims. This Proof of Claim is in addition to and cumulative of any other proof of claim or proof of administrative expense claim, which may have been filed or will be filed by the Claimant in the Debtor's bankruptcy case.

67. By filing this Proof of Claim, the Claimant (a) does not submit to the jurisdiction of this Court for any purpose other than with respect to the Roanoke Suits and the Potential Roanoke Claims, (b) does not waive any (and expressly reserves all) of its procedural and substantive defenses to any claim that may be asserted against the Claimant by the Debtor, any trustee of any of the Debtor's estate, any affiliate of the Debtor, or any other person, (c) does not waive (and expressly reserves) any claim, right or right of action that the Claimant has or might have against the Debtor or any Debtor affiliate or any other person, whether such claim, right or action arises prior to, upon or after the commencement of the above-captioned chapter 11 case, and (d) does not waive (and expressly reserves) any and all other rights that it may have pursuant to applicable law or agreement.

[*Remainder of Page Intentionally Left Blank*]

68. All notices, objections, or other communications relating to the Proof of Claim should be addressed and sent to:

Center for Diagnostic Imaging/Insight Imaging
Attn: General Counsel
5775 Wayzata Boulevard, Suite 400
Minneapolis, MN 55416
(952) 543-6500 (telephone)

With copies to:

Ron E. Meisler, Esq.
Renu P. Shah, Esq.
SKADDEN, ARPS, SLATE, MEAGHER
& FLOM LLP
155 North Wacker Drive
Chicago, Illinois 60606
(312) 407-0700 (telephone)
(312) 407-0411 (facsimile)
Email: Ron.Meisler@Skadden.com
Renu.Shah@Skadden.com

[EXHIBIT A]

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	83.604	104.5%	HPLC	5/23/2012

alex tang - Laboratory Supervisor

05/24/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 176896-01
LOT #: 05212012@68
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 05/22/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	05/22/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	05/23/2012

Amar Arafat - Microbiologist

06/05/2012
Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.451	101.8%	HPLC	7/5/2012

Alex Tang - Laboratory Supervisor

07/05/2012
Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 180509-01
LOT #: 06292012@26
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 07/03/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL amber vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP 71	07/03/2012
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	07/06/2012

Sample properties cause turbidity in growth media. Per USP 71; the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Amar Arafat - Microbiologist

07/17/2012
Date Reported

Sterility - 14 day sterility report. In accordance with the USP guidelines, the samples will be incubated for 14 days.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V4 03/05/2010

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Methylprednisolone Acetate Specifications = 90% - 110%	80	mg/mL	81.676	102.1%	HPLC	8/15/2012

Alex Tang - Laboratory Supervisor

08/15/2012
Date

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Endotoxin	6.25 EU/mg	<0.05 EU/mg	USP 85	08/16/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany D. Hyde

Tiffany Hyde - Microbiologist

08/17/2012
Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

ANALYTICAL RESEARCH LABORATORIES
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 184460-01
LOT #: 08102012@51
DESCRIPTION: Methylprednisolone AC (PF) 80 mg/mL Injection
DATE RECEIVED: 08/14/2012
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Two 5 mL clear vials

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days	USP 71	08/14/2012

Sample properties cause turbidity in growth media. Per USP 71, the sample will be inoculated into new growth media after 14 days of incubation and incubated for 4 additional days.

Tiffany O. Hyde

Tiffany Hyde - Microbiologist

08/28/2012
Date Reported

Sterility – 14 day sterility report. In accordance with the USP guidelines, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the USP guidelines, the sample was incubated for 14 days.

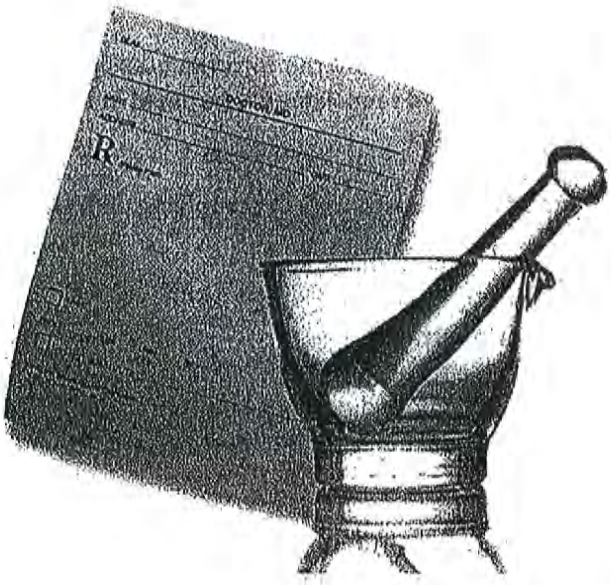
Results reported above relate only to the sample that was tested.

ARL Form QUF-078-V5 08/20/2012

[EXHIBIT B]

Framingham, MA Facility
Q2 2012 – Ending June 30, 2012

Quality Assurance REPORT CARD



New England Compounding Center

697 Waverly Street
Framingham, MA 01702
(800) 994-6322

We are pleased to present our Quality System Report Card for the 2nd Quarter 2012, ending June 30th, 2012.

Our Report Card summarizes the results of our most recent review of NECC's product, personnel, facilities and quality systems. This Report Card may be kept on file and referred to during various hospital inspections by the Joint Commission and your local, state, and federal regulatory agencies as third party service provider substantiation.

The NECC Quality System Report Card is in place to evaluate our internal quality systems each quarter to ensure that we are meeting the associated requirements outlined in USP <797> "Pharmaceutical Compounding – Sterile Preparations."

NECC's Quality System Report Card assists all of our customers in complying with USP <797>.

Our Commitment

NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers.

The results of our internal review for the 2nd Quarter 2012, ending June 30th, demonstrate that NECC meets and is in continued compliance with all applicable requirements and standards. This review exhibits that our existing quality systems and facilities are in a state of control.

All information contained within this document is confidential and not intended for reproduction or distribution without prior written approval.

Barry J. Cadden

Barry J. Cadden, R.Ph
Pharmacy Director

CONTENTS

Product Quality 4

- End Product Testing – Sterility/Endotoxin/Quantitative Analysis
  - Sterility Testing Success Rate
  - Endotoxin Testing Success Rate
  - Quantitative Testing Success Rate

Personnel 5

- Media Fill Monitoring
  - Media Fill Success Rate
- Gloved Fingertip Monitoring
  - Personnel Monitoring Excursion Rate

Facility 6-7

- ISO 4/5 Hoods
  - ISO 4/5 Hood Surface Monitoring Excursion Rate
  - ISO 4/5 Hood Air Monitoring Excursion Rate
- Clean Room Areas
  - Clean Room Surface Monitoring Excursion Rate
  - Clean Room Air Monitoring Excursion Rate

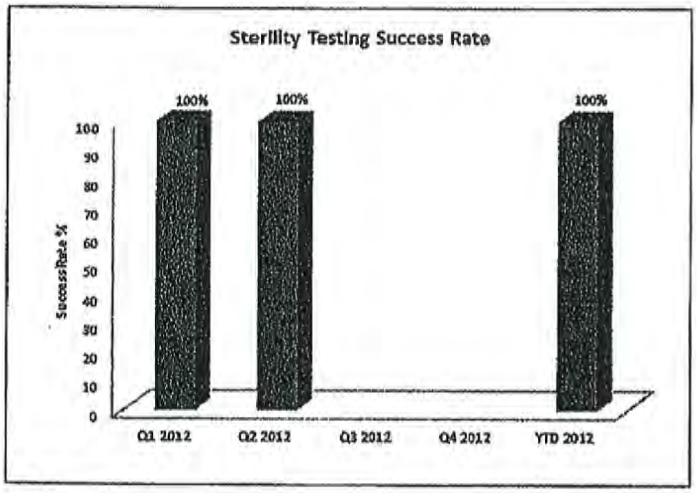
Customer Satisfaction 8-9

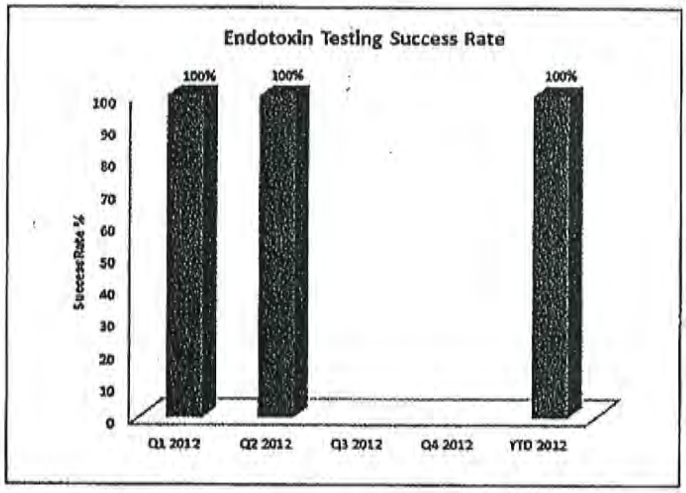
- Overall
  - Customer Satisfaction Success Rate per Units Shipped
- By Category
  - Customer Complaint Rate: Product, Packaging, Labeling
  - Customer Complaint Rate: Packing / Shipping
  - Customer Complaint Rate: Patient Response
  - Customer Complaint Rate: Other

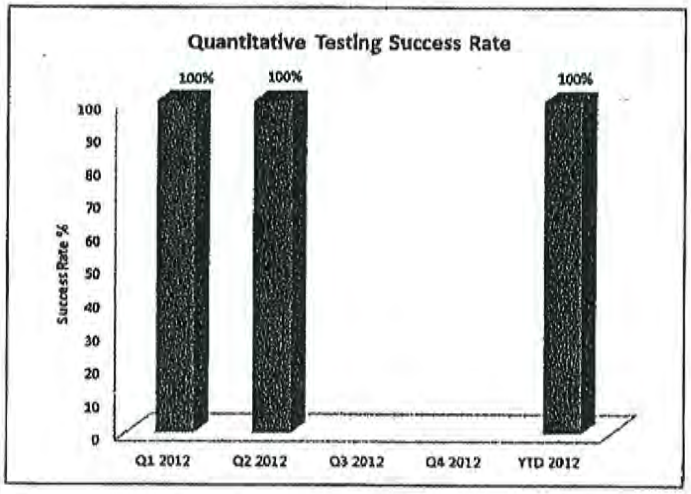
PRODUCT QUALITY

End Product Testing – Sterility/ Endotoxin/ Quantitative Analysis

NECC's extensive end product testing program exceeds basic USP <797> compliance and ensures product quality.



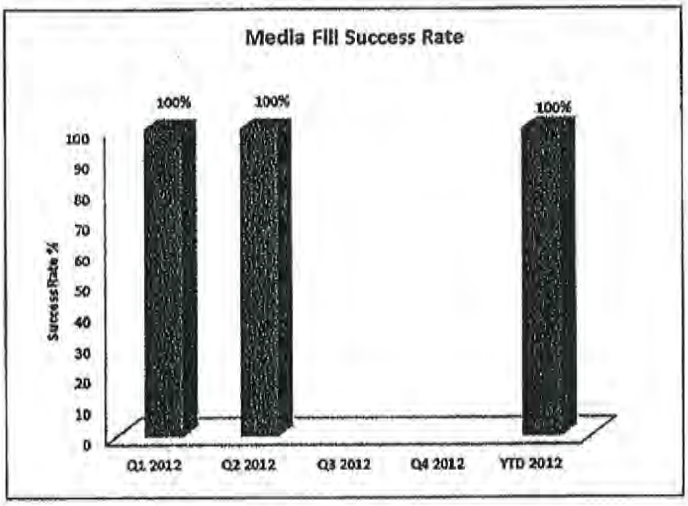




Personnel

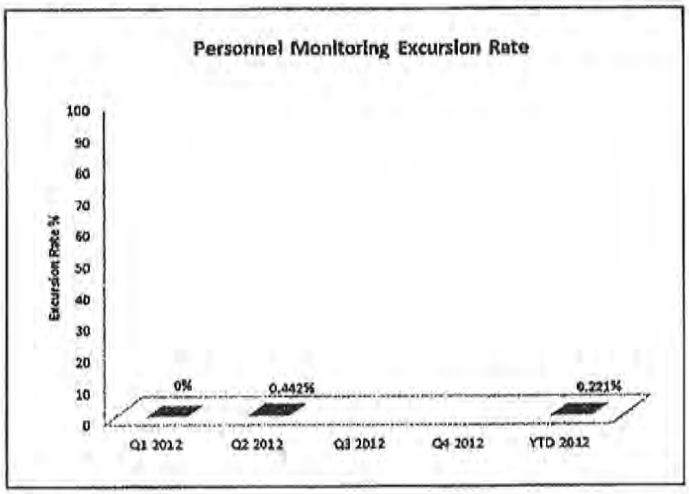
Media Fill Monitoring

Personnel who perform compounding activities must perform initial and biannual media fills as per USP <797> to ensure rigorous aseptic technique.



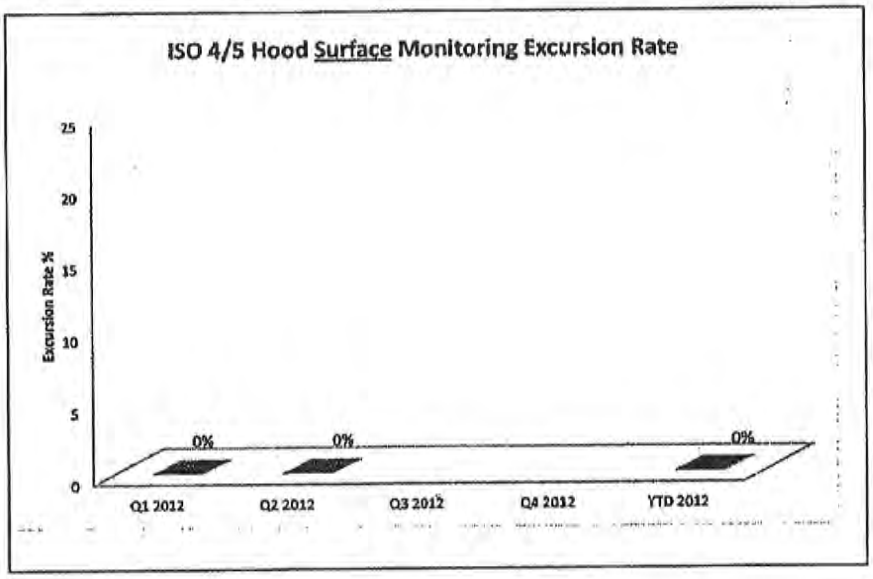
Gloved Finger Tip Monitoring

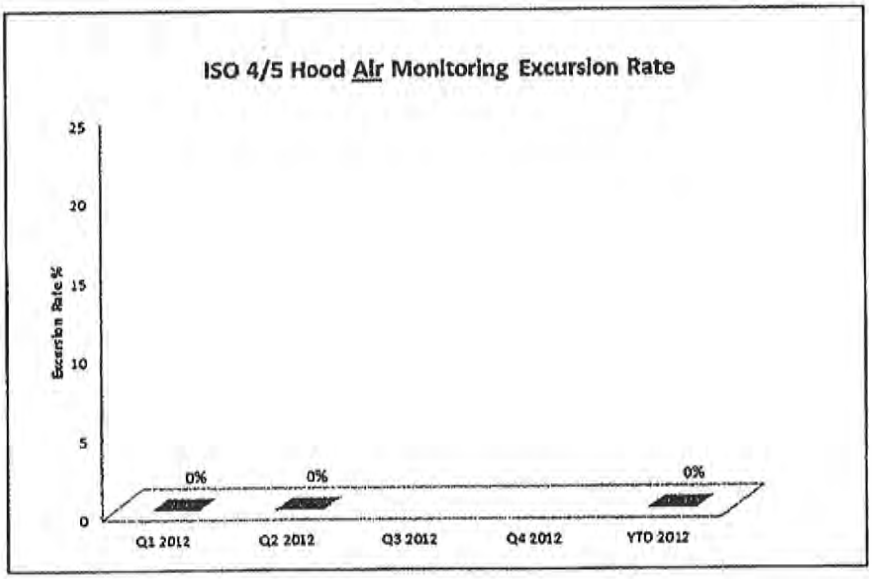
Touch plate sampling of gloved finger tips is performed routinely on each person performing aseptic compounding tasks.



Facility – ISO 4/5 Hoods

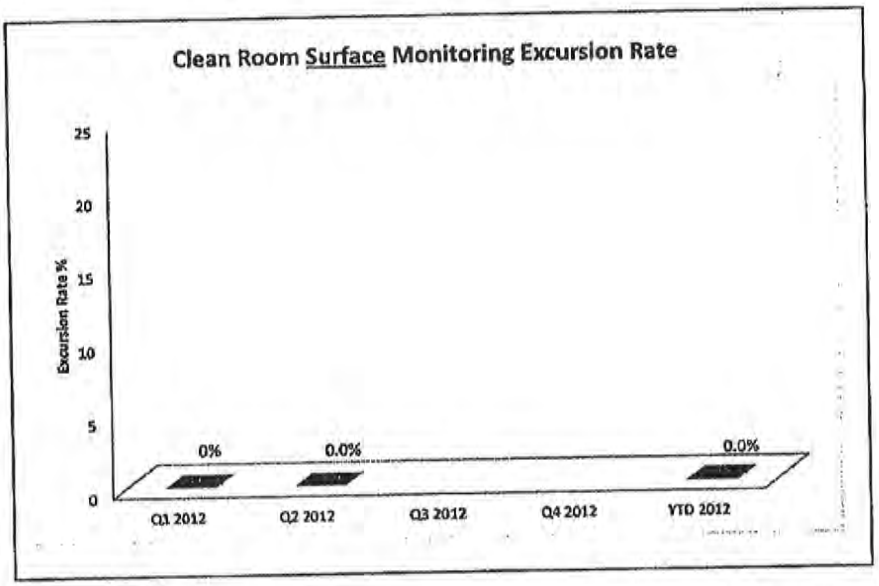
NECC has established an extensive environmental monitoring program for surface and air samples for ISO 4/5 Hoods to ensure preparations are compounded in the cleanest environment possible and to document compliance with the requirements in USP <797>.

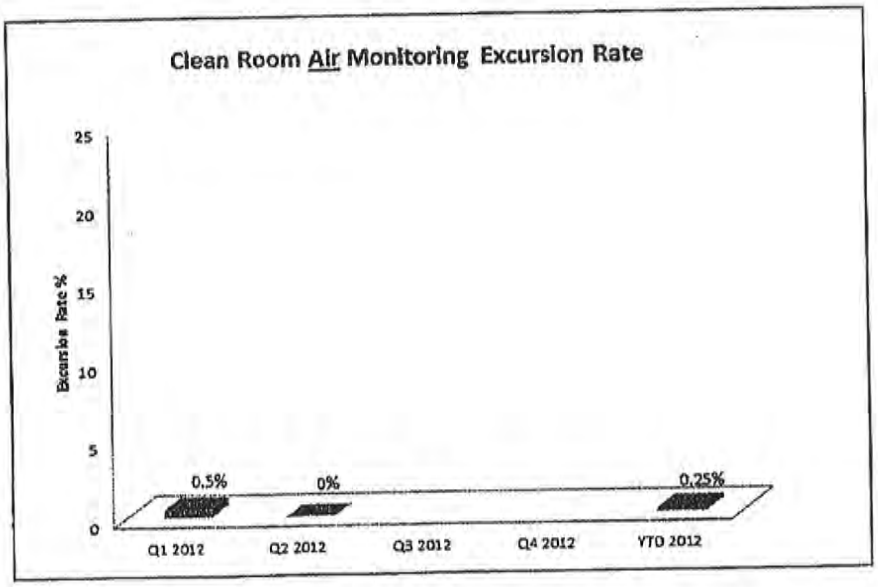




Facility – Clean Room Areas

NECC has established an extensive environmental monitoring program for surface and air samples for clean room areas to ensure preparations are compounded in the cleanest environment possible and to document compliance with the requirements in USP <797>.



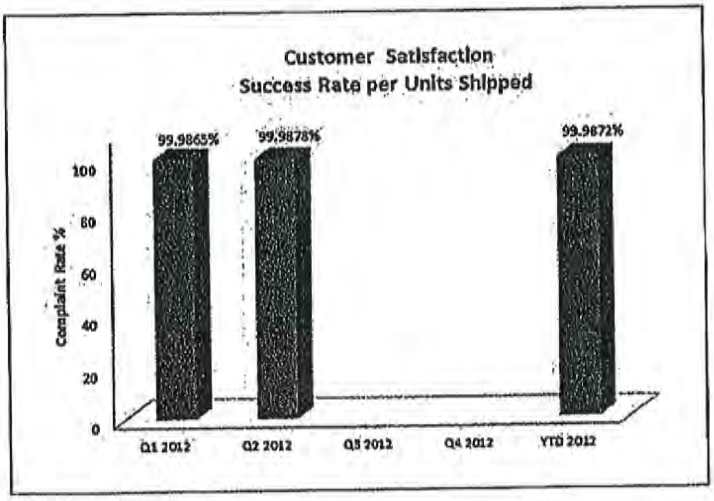


CUSTOMER SATISFACTION

NECC has a formal program to document and promptly investigate customer complaints related to quality issues per USP <797> requirements. Product impact and potential for adverse events are evaluated. Corrective actions are implemented as necessary to prevent future events. Trending of complaints is performed and reviewed quarterly to help us improve our systems.

Overall

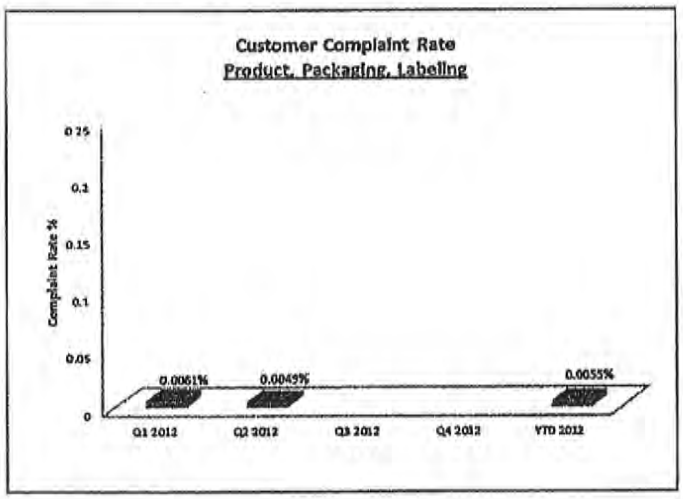
Data from Q2 2012 indicate that NECC has a very low customer complaint rate of 0.0122%. This low overall complaint rate indicates the preparations made by NECC are consistently made and delivered correctly.

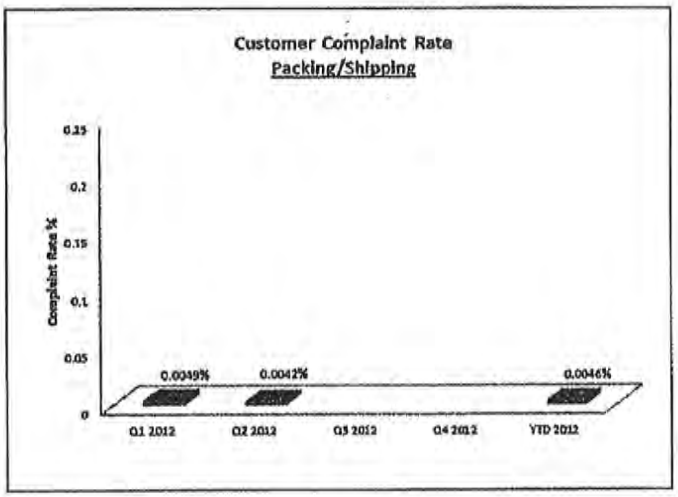


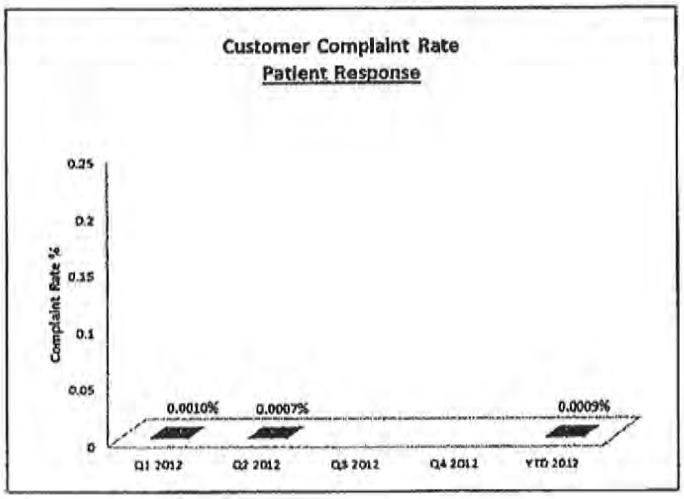
CUSTOMER SATISFACTION

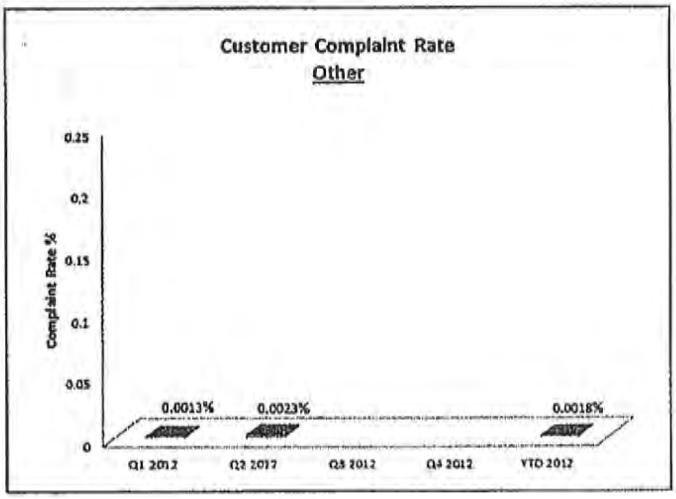
By Category

Customer complaints are assigned to categories. During Q2 2012, customer complaints were broken into 4 categories. The breakdown of customer complaints by category can be seen in the figure below.









[EXHIBIT C]

NECC
advancing pharmacy solutions
697 Waverly Street Framingham, MA 01702
(508) 820-0606, (800) 994 – NECC
Fax (508) 820-1616 or (888) 820 - 0583
www.neccrx.com

To: Dr. Robert O' Brien
The Center for Surgical Excellence
From: Linda Pino
Phone: 800-994-6322 ext 611
Fax: 508-820-1616

Subject: *Do you need help obtaining medications?*

Date: 5/18/2007

Good Morning Dr. O' Brien;

I want to thank you very much for taking the time to review the attached information about New England Compounding Center and our services. We are supplying pain physicians throughout the states with the preservative free injectables. Attached for your review is information about the customized pharmacy services we supply to Doctors, Surgery Centers and Hospitals across the United States.

If you have any questions, please feel free to contact me directly at 800-994- 6322, Ext.611. We appreciate the opportunity to serve you and your patients.

Best regards,

Linda Pino
Account Manager
NECC Pharmacy

Company Overview

NECC is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and service from our state-of-the-art facility.

Compounding allows a practioner to prescribe, and a pharmacist to prepare, medications that are:

- No longer manufactured
- Persistently backordered due to production shortages
- Not commercially available in the combination or dosage form the patient needs, i.e. preservative free

Why NECC?

- Complies with USP Chapter 797 Guidelines for Aseptic Compounding
- Our facility was designed and built as a compounding-only pharmacy with a strong focus on sterile products
- Sterile fluids and injectables are prepared in a Class 10 Microenvironment (barrier isolator), and our electronic analytical balances ensure accurate weighing
- Our clinically trained pharmacists
  - Are licensed and registered by the Massachusetts Board of Registration in Pharmacy
  - Have completed American Council on Pharmaceutical Education accredited aseptic training courses
  - Follow national standards of practice for sterile product preparation as set forth by professional associations such as the American Society of Health-System Pharmacists (ASHP) and the United States Pharmacopeia (USP)
  - Are members of the International Academy of Compounding Pharmacists (IACP) and the Massachusetts Pharmacists Association (MPhA)
  - Use only the highest quality ingredients and the latest techniques
  - Maintain extensive Environmental Testing and Quality Assurance Programs
  - Use an independent lab to test applicable medications for sterility, potency and pyrogenicity

NECC has earned a national reputation as a provider of high quality compounded medications and excellent service to patients and prescribers.

advancing pharmacy solutions
necc

697 Waverly Street
Framingham, MA 01702
Phone: 508-820-0606 Fax: 508-820-1616
www.neccrx.com

V62606

advancing pharmacy solutions
necc

697 Waverly Street, Framingham, MA 01702
Tel: 800.994.6322 or 508.820.0606
Fax: 888.820.0583 or 508.820.1616
www.neccrx.com mail@neccrx.com

General Overview of Policies & Procedures for Compounding Sterile Products

NECC operates in accordance with the following general guidelines when compounding sterile products:

A. Facility/Equipment
   a. Class 10 Microenvironments (barrier isolator).
   b. Certified by Massachusetts Board of Pharmacy (tel: 617-727-9953) as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board regulations, 247 CMR 6.01 (6) (c).

B. Monitoring & Maintenance
   Class 10 Microenvironments validated every 6 months by Scientific Air Analysis, Inc. of Ashland, MA (tel: 508-881-7100).

C. Personnel
   a. All sterile compounding is performed by properly trained and validated registered pharmacists (no technicians).
   b. Pharmacy personnel are trained/validated by an outside agency, Professional Compounding Centers of America (PCCA).
   c. Personnel are validated on a quarterly basis.

D. Quality Assurance/Quality Control
   a. USP Chemicals are obtained only from FDA registered facilities.
   b. Formulations are sterilized by either filtration through a 0.22 micron filter or by autoclaving.
   c. Samples from final product batch lots are sent to an independent lab, Analytical Research Laboratories in Oklahoma City, OK (tel: 405-271-1144) for sterility, endotoxin (pyrogenicity), and potency testing.
   d. Tested medication is quarantined and dispensed only after sample has tested negative for endotoxin and microbial contamination.
   e. The Quality Assurance Team (QAT) made up of employees from all departments within NECC, meets regularly to review all quality related items.

f. NECC maintains strict environmental testing protocols. Results of these tests are reported at all QAT meetings.
g. All sterile compounding actions are performed in compliance with NECC's Standard Operating Procedures (SOPs). These SOPs have been "mapped" against USP 797 "Pharmaceutical Compounding – sterile preparations" to insure that all USP 797 requirements are observed.
h. All pharmacy operations are reviewed and certified by an outside USP 797 expert consultant regularly.

E. Use-by Dating

Each vial is labeled with a use-by date appropriate to the formulation.

F. Packaging

Compounded preparations are packaged in containers meeting USP standards. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility.

H. Shipping

Medications are shipped overnight (usually via FedEx) in an appropriate container to ensure controlled temperatures and product integrity.

I. Licensing

NECC has undertaken a rigorous licensure process thus giving us the ability to legally dispense prescription medication in all 50 states.

advancing pharmacy solutions
necc

697 Waverly Street, Framingham, MA 01702
Tel: 800.994.6322 or 508.820.0606
Fax: 888.820.0583 or 508.820.1616
www.neccrx.com mail@neccrx.com

General Overview of Policies & Procedures for Compounding Sterile Products

NECC operates in accordance with the following general guidelines when compounding sterile products:

A. Facility/Equipment
   a. Class 10 Microenvironments (barrier isolator).
   b. Certified by Massachusetts Board of Pharmacy (tel: 617-727-9953) as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board regulations, 247 CMR 6.01 (6) (c).

B. Monitoring & Maintenance
   Class 10 Microenvironments validated every 6 months by Scientific Air Analysis, Inc. of Ashland, MA (tel: 508-881-7100).

C. Personnel
   a. All sterile compounding is performed by properly trained and validated registered pharmacists (no technicians).
   b. Pharmacy personnel are trained/validated by an outside agency, Professional Compounding Centers of America (PCCA).
   c. Personnel are validated on a quarterly basis.

D. Quality Assurance/Quality Control
   a. USP Chemicals are obtained only from FDA registered facilities.
   b. Formulations are sterilized by either filtration through a 0.22 micron filter or by autoclaving.
   c. Samples from final product batch lots are sent to an independent lab, Analytical Research Laboratories in Oklahoma City, OK (tel: 405-271-1144) for sterility, endotoxin (pyrogenicity), and potency testing.
   d. Tested medication is quarantined and dispensed only after sample has tested negative for endotoxin and microbial contamination.
   e. The Quality Assurance Team (QAT) made up of employees from all departments within NECC, meets regularly to review all quality related items.

f. NECC maintains strict environmental testing protocols. Results of these tests are reported at all QAT meetings.
g. All sterile compounding actions are performed in compliance with NECC's Standard Operating Procedures (SOPs). These SOPs have been "mapped" against USP 797 "Pharmaceutical Compounding – sterile preparations" to insure that all USP 797 requirements are observed.
h. All pharmacy operations are reviewed and certified by an outside USP 797 expert consultant regularly.

E. Use-by Dating

Each vial is labeled with a use-by date appropriate to the formulation.

F. Packaging

Compounded preparations are packaged in containers meeting USP standards. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility.

H. Shipping

Medications are shipped overnight (usually via FedEx) in an appropriate container to ensure controlled temperatures and product integrity.

I. Licensing

NECC has undertaken a rigorous licensure process thus giving us the ability to legally dispense prescription medication in all 50 states.

Prescription Order Form

DATE: _____

697 Waverly Street, Framingham MA 01702
800.994.6322, 508.820.0606.
FAX 888.820.0583 or 508.820.1616

NAME OF FACILITY: _____ **PHONE NUMBER:** _____

ADDRESS: _____ **P.O. #:** _____

We **must** have Facility name & address to process your prescription order – *Thank you.*

Name of Patient	Name of medication to be compounded	Strength (%, mg/ml, u/ml)	If *preservative-free,* write in p/f	Vial size (mls)	# of vials	Sig:

Physician's Name/Signature: _____ **DEA Number:** _____

Verification: Institutional Agent: _____ **NECC Agent:** _____ **Date:** _____ **Time:** _____

V113006

Attn: Linda Pino

Account Information/ Credit Application

Shipping Address:

Facility Name: _____

Street: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ Email: _____

Shipping Contact Name: _____

Billing Address:

Facility Name: _____

Street: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ Email: _____

Accounts Payable Contact Name: _____

ARE PURCHASE ORDERS REQUIRED? Yes_____ No_____ PO#_____

DO YOU PAY BY CREDIT CARD? Yes_____ No_____

Type _____ Number_____ Exp Date_____

Bank Reference:

Bank Name:_____ Contact Name:_____ Phone:_____

Bank Account #:_____ Type: _____

Bank Address, City, State, Zip:_____

Trade Reference:

Company Name	Contact Address	City	State	Zip	Phone
1.					

The signature below represents and warrants that the party signing below is an authorized representative of the company and that the information provided herein is a complete and accurate representation of the company's financial situation as of the date hereof and that the party authorizes trade and bank references to release any information necessary to assist in establishing a line of credit.

Name:_____ Title:_____

Signature: _____ Date:_____

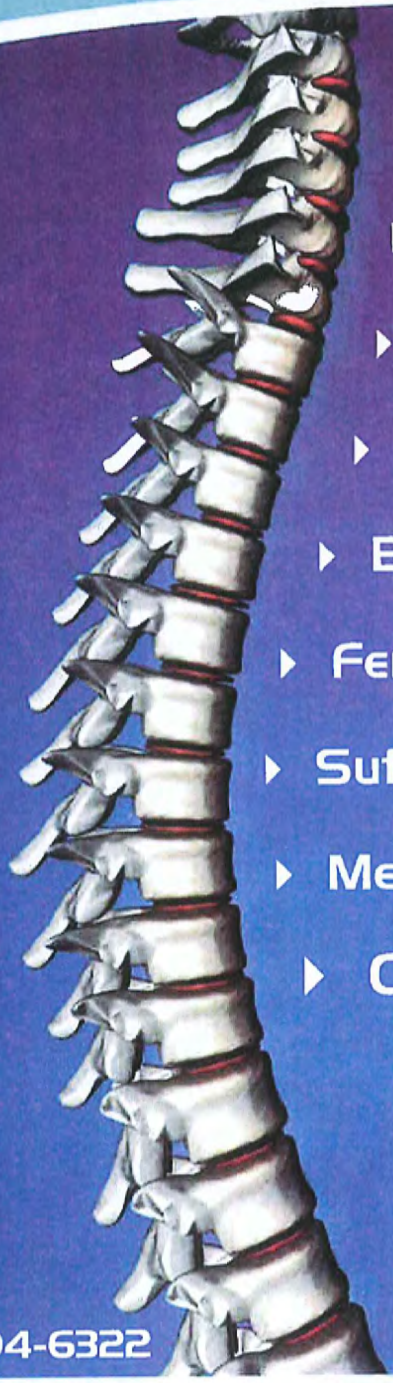
V102005

advancing pharmacy solutions

necc

Attn: Linda Rino
697 Waverly Street, Framingham, MA 01702
T 800-994-6322 or 508-820-0606
F 888-820-0583 or 508-820-1616
www.neccrx.com mail@neccrx.com

PRESERVATIVE-FREE INTRATHECAL PUMP REFILLS



- Baclofen
- Morphine
- Hydromorphone
- Clonidine
- Bupivacaine
- Fentanyl
- Sufentanil
- Meperidine
- CUSTOM COMBINATIONS

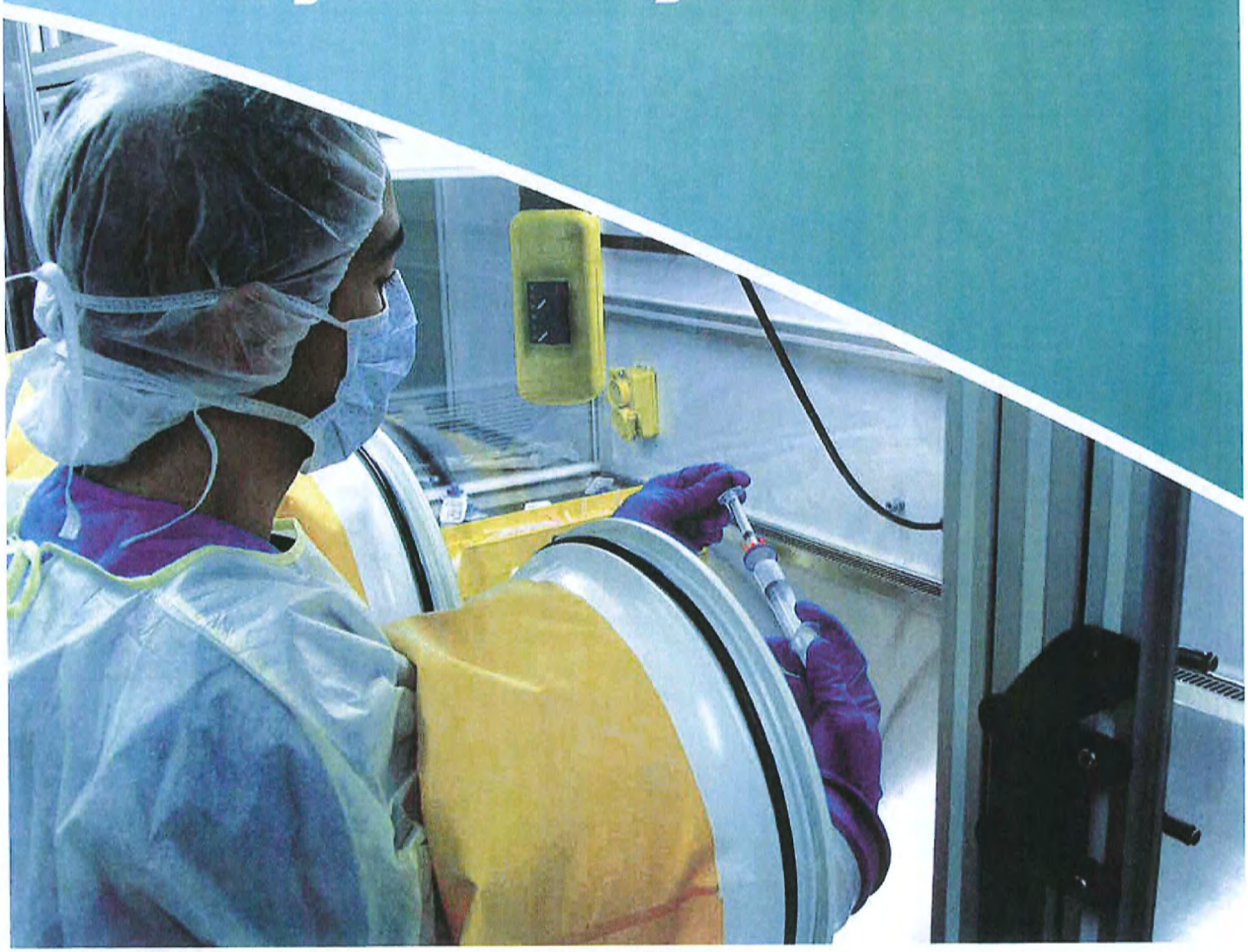
advancing pharmacy solutions
necc

www.neccrx.com

800-994-6322

USP 797

- Class 10 barrier isolator
- Environmental monitoring programs
- End product testing programs
- Quality assurance programs
- Long term stability data



[EXHIBIT D]

Exhibit D
LAWSUITS AGAINST INSIGHT HEALTH CORP.
(The Roanoke Lawsuits)

Case	Docket No.	Filed	Court
1. *Sharon Wingate, Executor of the Estate of Douglas Gray Wingate, Deceased, v. Insight Health Corp., et al.*	CL12002547	12/27/2012	Roanoke City Circuit Court
2. *Trudy R. Epperly v. Insight Health Corp., et al.*	CL12002571	12/28/2012	Roanoke City Circuit Court
3. *James Wirt Smith v. Insight Health Corp., et al.*	CL12002572	12/28/2012	Roanoke City Circuit Court
4. *Pauline R. McFarlane v. Insight Health Corp., et al.*	CL12002573	12/28/2012	Roanoke City Circuit Court
5. *Chester T. Kalinoski v. Insight Health Corp., et al.*	CL12002574	12/28/2012	Roanoke City Circuit Court
6. *Barbara J. Filson v. Insight Health Corp., et al.*	CL12002575	12/28/2012	Roanoke City Circuit Court
7. *Dana Marlene Bradley v. Insight Health Corp., et al.*	CL12002576	12/28/2012	Roanoke City Circuit Court
8. *Zachary Lucas Foutz, a Minor, by His Parents and Next Friends, Benjamin T. Foutz and Andrea L. Foutz v. Insight Health Corp., et al.*	CL13000009	1/2/2013	Roanoke City Circuit Court
9. *Richard A. Whitlow v. Insight Health Corp., et al.*	CL13000054	1/7/2013	Roanoke City Circuit Court
10. *Robert Earl Harris, Jr. v. Insight Health Corp., et al.*	CL13000055	1/7/2013	Roanoke City Circuit Court
11. *Randolph E. Smith v. Insight Health Corp., et al.*	CL13000057	1/8/2013	Roanoke City Circuit Court

12. *Julian Delano Holbrook v. Insight Health Corp., et al.*	CL13000370	2/11/2013	Roanoke City Circuit Court
13. *Ronald T. Courtney v. Insight Health Corp., et al.*	CL13000417	2/15/2013	Roanoke City Circuit Court
14. *Chance Everett Baker v. Alaunus Pharmaceutical., LLC, et al.*	CL13000451	2/21/2013	Roanoke City Circuit Court
15. *Ferman W. Wertz v. Alaunus Pharmaceutical., LLC, et al.*	CL13000452	2/21/2013	Roanoke City Circuit Court
16. *Patrick O. Johnston v. Alaunus Pharmaceutical., LLC, et al.*	CL13000453	2/21/2013	Roanoke City Circuit Court
17. *Ronald A. Brown v. Insight Health Corp., et al.*	CL13000538	3/1/2013	Roanoke City Circuit Court
18. *Robert Dana Bender, Executor of the Estate of Ralph James Irace, Jr., Deceased v. Insight Health Corp., et al.*	CL13000577	3/6/2013	Roanoke City Circuit Court
19. *Odessa M. Shuck v. Insight Health Corp., et al.*	CL13000584	3/7/2013	Roanoke City Circuit Court
20. *Rose M. White v. Insight Health Corp., et al.*	CL13000606	3/8/2013	Roanoke City Circuit Court
21. *Patricia S. Brown, et al. v. Insight Health Corp., et al.*	CL13000607	3/8/2013	Roanoke City Circuit Court
22. *Sandra F. Artis v. Insight Health Corp., et al.*	CL13001105	5/10/2013	Roanoke City Circuit Court